

REMARKS

In the Office Action mailed June 16, 2006, the Examiner rejected Claims 25-59 under 35 U.S.C. §103(a). Each rejection is addressed below.

I. Rejection of Claims 25-59 under 35 U.S.C. §103(a)

Claims 25-59 are rejected under 35 U.S.C. §103(a) as being anticipated by Foldvari, et al., (2000) J. Controlled Release, Volume 66, 15 May 2000, pages 199-214 (hereinafter, “the Foldvari reference”), Baker et al., (1996) Nucleic Acids Research vol. 24, pages 2176-2182 (hereinafter, “the Baker reference”), U.S. Patent No. 6,267,987 (hereinafter, “the ‘987 patent”), and Baldwin, et al., (1998) Advanced Drug Delivery Reviews 33, pages 71-86 (hereinafter, “the Baldwin reference”). In particular, the Examiner stated, “Foldvari¹ discloses transdermal delivery of protein or nucleotide to the skin tissue (pp. 71-86). Foldvari discloses on page 205 that dendrimers are known to deliver DNA. Baker discloses the use of dendrimers to deliver DNA (pp 2176-2182). The combination of Foldvari and Baker discloses the use of dendrimers for the delivery of proteins or DNA. The combined reference failed to disclose the presence of polyester for the delivery. But Park discloses as carriers for delivery of nucleic acids.” Office Action, page 3. The Applicants respectfully disagree.

The Examiner has not identified where an alleged motivation to combine the cited references exists within the actual references. In particular, the Examiner stated, “it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teaching of Foldvari and Baker for the delivery of DNA or protein. One having ordinary skill in the art would have been motivated to incorporate polyesters with dendrimer and expect to successfully deliver DNA.” However, the Examiner does not indicate where within the cited references such an alleged motivation exists and provides no evidence to substantiate the alleged expectation of success. As an obviousness rejection requires an actual showing of where within a prior art reference an alleged suggestion or motivation to combine references exists (or a motivation from some other evidentiary source), so too must the Examiner in the present case provide the locations within the cited references motivating their combination. MPEP §2143. Absent identification of a location within the cited references indicating a motivation to combine

¹ The cited page reference pertains to the Baldwin reference. As such, the Applicants presume the noted sentence refers to the Baldwin reference and not the Foldvari reference.

the references in the manner suggested by the Examiner, the rejection cannot stand. The Applicants request these rejections be withdrawn.

The Examiner has not described how the cited references provide a reasonable expectation of successfully obtaining the claimed invention upon combination of the cited references. In particular, the Examiner stated, “One having ordinary skill in the art would have been motivated to incorporate polyesters with dendrimer and expect to successfully deliver DNA.” The Examiner’s “expectation” statement fails to indicate how and where the cited references lead one skilled in the art toward a reasonable expectation of successfully obtaining the claimed invention upon combination of the references. Indeed, the Federal Circuit has dictated that in evaluating obviousness, an Examiner must look to see if “the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable expectation of success, viewed in light of the prior art... **Both the suggestion and the expectation of success must be founded in the prior art**, not the applicant’s disclosure.” See, *In re Dow Chem.*, 837 F.2d 469, 471 (Fed. Cir. 1988) (emphasis added). As the Examiner has not indicated that the expectation of success is founded in the cited references and where within the cited references such a founding exists, the Examiner’s rejection cannot stand. The Applicants request these rejections be withdrawn.

Moreover, the Applicants now amend Claim 1 such that the phrase, “contacting said tissue with said composition” is now replaced with the phrase, “contacting said tissue with said composition *such that said biological agent is provided to said tissue at biologically active concentrations.*” Support for this amendment is located throughout the Specification. The cited references provide no expectation of successfully obtaining the claimed invention (e.g., a method comprising contacting a tissue with a composition comprising a membrane associated with at least one dendrimer comprising at least one biological agent such that the biological agent is provided to the tissue at biologically active concentrations) upon combination of the cited references. For example, the cited references provide no guidance as to what amount (if any) of dendrimer associated bioagents is available to function at the tissue. For example, the art does not teach or suggest that membrane associated dendrimers are bioavailable, stable, or physically oriented so as to have activity. The Applicants request the claims be passed into allowance.

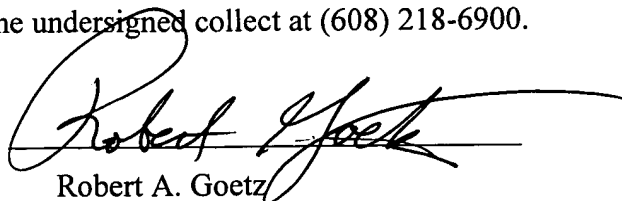
II. Dependent Claims

The Applicants further note that the Examiner has ignored the dependent claims in the claim set. For example, the Examiner has not addressed the claim elements described in Claims 26 (wherein said tissue comprises cultured cells), Claim 32 (wherein said membrane comprises a biocompatible membrane), Claim 33 (wherein said membrane comprises a bioerodable membrane), Claim 34 (wherein said membrane is desiccated), Claim 35 (wherein said membrane comprises a PLGA membrane), Claim 36 (wherein said membrane comprises a collagen membrane), Claim 37 (wherein said dendrimer is covalently attached to said membrane), Claim 43 (wherein said agent comprises a therapeutic agent), Claim 46 (wherein said DNA comprises a gene encoding a protein that promotes wound healing), Claim 47 (wherein said gene comprises a gene encoding a growth factor), Claim 48 (wherein said DNA comprises a gene encoding a protein that promotes tissue vascularization), Claim 49 (wherein said gene comprises a gene encoding a growth factor), Claim 51 (wherein said protein comprises a protein that promotes wound healing), Claim 52 (wherein said protein comprises a growth factor), Claim 53 (wherein said protein comprises a protein that promotes tissue vascularization), and Claim 54 (wherein said protein comprises a growth factor). In view of the lack of expectation of success highlighted above and the additional criteria imposed by some of these elements, the rejections cannot be maintained. As the Examiner has not addressed such dependent claims, the Applicants request these claims be passed into allowance.

CONCLUSION

Each rejection of the Office Action mailed June 16, 2006 has been addressed. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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